

Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

40

af

6

Attorney Docket Number

**COMPLETE IF KNOWN**

**Application Number** 09/463,098

**Filing Date** | May 15, 2000

**First Named Inventor** Nicosia, A. et al.

## Group Art Unit

**Examiner Name**

1627 1136

AUG 2002

RECEIVED

## U.S. PATENT DOCUMENTS

## **FOREIGN PATENT DOCUMENTS**

**Examiner  
Signature**

J. Wissenszky

**Date Considered**

5/14/04

\*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609.

Draw line through citation if not in conformance and not considered.

Include copy of this form with next communication to applicant.

Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE****STATEMENT BY APPLICANT**

AUG 16 2002 (use as many sheets as necessary)

PATENT &amp; TRADEMARK OFFICE

Sheet 2

of

6

Attorney Docket Number

IT0019P

COMPLETE IF KNOWN

Application Number	09/463,098
Filing Date	May 15, 2000
First Named Inventor	Nicosia, A. et al.
Group Art Unit	307 1627
Examiner Name	Bhatti, T. <i>Wissner</i>

RECEIVED  
TECH CENTER 1600  
AUG 20 2002  
U.S. PATENT & TRADEMARK OFFICE**OTHER NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No.	Include name of the author, title, date, page(s), volume-issue number(s) and place of publication.
A	Cormack, B. et al. "Regional Codon Randomization: Defining a TATA-Binding Protein Surface Required for RNA Polymerase III Transcription", Science, 1993, Vol. 262, pp. 244-248	
B	Cortese, R. et al. "Epitope discovery using peptide libraries displayed on phage", Trends Biotechnol, 1994, Vol. 12, pp. 262-267	
C	Cortese, R. et al. "Selection of biologically active peptides by phage display of random peptide libraries", Current Opinion in Biotechnology, 1996, Vol. 7, pp. 616-621	
D	Farci, P. et al. "Prevention of hepatitis C virus infection in chimpanzees after antibody-mediated <i>in vitro</i> neutralization", Proc Natl Acad Sci USA, 1994, Vol. 91, pp. 7792-7796	
E	Farci, P. et al. "Prevention of hepatitis C virus infection in chimpanzees by hyperimmune serum against the hypervariable region 1 of the envelope 2 protein", Proc Natl Acad Sci USA, 1996, Vol. 93, pp. 15394-15399	
F	Folgari, A. et al. "A general strategy to identify mimotopes of pathological antigens using only random peptide libraries and human sera", The EMBO Journal, 1994, Vol. 13, pp. 2236-2243	
G	Major, M. et al. "DNA-Based Immunization with Chimeric Vectors for the Induction of Immune Responses against the Hepatitis C Virus Nucleocapsid", Journal of Virology, 1995, Vol. 69, pp. 5798-5805	
H	Mecchia, M. et al. "Nonrheumatoid IgM in Human Hepatitis C Virus-Associated Type II Cryoglobulinemia Recognize Mimotopes of the CD4-Like LAG-3 Protein", The Journal of Immunology, 1996, Vol. 157, pp. 3727-3736	
I	Meola, A. et al. "Derivation of Vaccines From Mimotopes. Immunologic Properties of Human Hepatitis B Virus Surface Antigen Mimotopes Displayed on Filamentous Phage", The Journal of Immunology, 1995, Vol. 154, pp. 3162-3172	
J	Pessi, A. et al. "Application of the Continuous-flow Polyamide Method to the Solid-phase Synthesis of a Multiple Antigen Peptide (MAP) based on the Sequence of a Malaria Epitope", J of Chem Soc, Chemical Communications, 1990, Vol. 1, pp. 8-9	
K	Prezzi, C. et al. "Selection of Antigenic and Immunogenic Mimics of Hepatitis C Virus Using Sera from Patients", The Journal of Immunology, 1996, Vol. 156, pp. 4504-4513	
L	Scarselli, E. et al. "Occurrence of Antibodies Reactive with More than One Variant of the Putative Envelope Glycoprotein (gp70) Hypervariable Region 1 in Viremic Hepatitis C Virus-Infected Patients", Journal of Virology, 1995, Vol. 69, pp. 4407-4412	
M	Shimizu, Y. et al. "Evidence for <i>in vitro</i> replication of hepatitis C virus genome in a human T-cell line", Proc Natl Acad Sci USA, 1992, Vol. 89, pp. 5477-5481	
N	Simmonds, P. et al. "Classification of hepatitis C virus into six major genotypes and a series of subtypes by phylogenetic analysis of the NS-5 region", Journal of General Virology, 1993, Vol. 74, pp. 2391-2399	
O	Tam, J. "Synthetic peptide vaccine design: Synthesis and properties of a high-density multiple antigenic peptide system", Proc Natl Acad Sci USA, 1988, Vol. 85, pp. 5409-5413	

Examiner Signature

*T. Wissner*

Date Considered

5/14/04

\*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609.

Draw line through citation if not in conformance and not considered.

Include copy of this form with next communication to applicant.

Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE****STATEMENT BY APPLICANT**

(use as many sheets as necessary)

PATENT &amp; TRADEMARK OFFICE

AUG 16 2002

3

of

6

Attorney Docket Number

IT0019P

**COMPLETE IF KNOWN**

Application Number	09/463,098
Filing Date	May 15, 2000
First Named Inventor	Nicosia, A. et al.
Group Art Unit	1629
Examiner Name	Bhatti, T.

TECH CENTER 2000 REC'D AUG 22 2002

<b>OTHER NON PATENT LITERATURE DOCUMENTS</b>		
Examiner Initials*	Cite No.	Include name of the author, title, date, page(s), volume-issue number(s) and place of publication.
TW	P	Weiner, A. et al. "Variable and Hypervariable Domains Are Found in the Regions of HCV Corresponding to the Flavivirus Envelope and NS1 Proteins and the Pestivirus Envelope Glycoproteins", Virology, 1991, Vol. 180, pp. 842-848
	Q	Winter G. et al. "Man-made antibodies", Nature, 1991, Vol. 349, pp. 293-299
	R	Kato, N. et al. "Characterization of Hypervariable Regions in the Putative Envelope Protein of Hepatitis C Virus", Biochem and Biophys Res Commun, 1992, Vol. 189, pp. 119-127
	S	Takeuchi, K. et al. "Hepatitis C viral cDNA clones isolated from a healthy carrier donor implicated in post-transfusion non-A, non-B hepatitis", Gene, 1990, Vol. 91, pp. 287-291
	T	Hohne, M. et al. "Sequence variability in the env-coding region of hepatitis C virus isolated from patients infected during a single source outbreak", Arch Virol, 1994, Vol. 137, pp. 25-34
	U	Wang, Y. et al. "Prevalence, Genotypes, and an Isolate (HC-C2) of Hepatitis C Virus in Chinese Patients With Liver Disease", Journal of Medical Virology, 1993, Vol. 40, pp. 254-260
	V	Okamoto, H. et al. "Molecular and clinical characteristics of the hepatitis C virus genotype "2c" found in Italians in Italy and France", International Hepatology Communications", 1995, Vol. 3, pp. 161-165
	W	Kato, N. et al. "Molecular cloning of the human hepatitis C virus genome from Japanese patients with non-A, non-B hepatitis", Proc Natl Acad Sci USA, 1990, Vol. 87, pp. 9524-9528
	X	Okamoto, H. et al. "The entire nucleotide sequence and classification of a hepatitis C virus isolate of a novel genotype from an Indonesian patient with chronic liver disease", Journal of General Virology, 1994, Vol. 75, pp. 629-635
	Y	Kato, N. et al. "Marked sequence diversity in the putative envelope proteins of hepatitis C viruses", Virus Research, 1992, Vol. 22, pp. 107-123
	Z	Sarashina, T. et al. "Nucleotide sequence of the hepatitis C virus genome from a patient negative for anti-HCV by the first generation antibody assay", Nucleic Acids Reserach, 1993, Vol. 21, pp. 1037
	AA	Tokita, H. et al. "Hepatitis C virus variants from Vietnam are classifiable into the seventh, eighth, and ninth major genetic groups", Proc Natl Acad Sci USA, 1994, Vol. 91, pp. 11022-11026
	BB	Abe, K. et al. "Genomic characterization and mutation rate of hepatitis C virus isolated from a patient who contracted hepatitis during an epidemic of non-A, non-B hepatitis in Japan", Journal of General Virology", 1992, Vol. 73, pp. 2725-2729
	CC	Okamoto, H. et al. "Characterization of the genomic sequence of type V (or 3a) hepatitis C virus isolates and PCR primers for specific detection", Journal of General Virology, 1993, Vol. 74, pp. 2385-2390
✓	DD	Seki, M. et al. "Effective production of hepatitis C virus core antigen having high purity in <i>Escherichia coli</i> ", Journal of Biotechnology, 1995, Vol. 38, pp. 229-241

Examiner Signature

T. *Winters*

Date Considered

5/14/04

\*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609.

Draw line through citation if not in conformance and not considered.

Include copy of this form with next communication to applicant.

Substitute for form 1449A/PTO

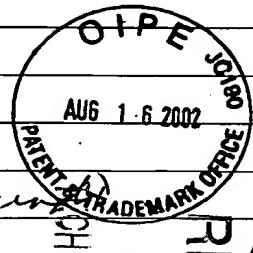
**INFORMATION DISCLOSURE**  
**STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 4 of 6 Attorney Docket Number IT0019P

**COMPLETE IF KNOWN**

Application Number	09/463,098
Filing Date	May 15, 2000
First Named Inventor	Nicosia, A. et al.
Group Art Unit	1629
Examiner Name	Bhatti, T.



RECEIVED  
PATENT & TRADEMARK OFFICE  
U.S. PATENT AND TRADEMARK OFFICE  
WILMINGTON, DE  
AUG 20 2002

**OTHER NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No.	Include name of the author, title, date, page(s), volume-issue number(s) and place of publication
Tan	EE	Kato, N. et al. Accession No. D12967 downloaded from Genbank VRL 28-May-1999
	FF	Takeuchi, K. et al. Accession Nos. D00574, D90080, M57585 downloaded from Genbank VRL 02-February-1999
	GG	Hall, W. et al. Accession No. L19383 downloaded from Genbank VRL 11-August-1994
	HH	Ogata, N. et al. Accession No. M62381 downloaded from Genbank VRL 10-June-1996
	II	Odeberg, J. et al. Accession No. U24616 downloaded from Genbank VRL 23-February-1996
	JJ	Odeberg, J. et al. Accession No. U24607 downloaded from Genbank VRL 23-February-1996
	KK	Kato, N. Accessoion No. X60573 downloaded from Genbank VRL 05-April-1992
	LL	Kato, N. et al. Accession No. D43650 downloaded from Genbank VRL 10-November-1997
	MM	Hohne, M. et al. Accession No. S73387 downloaded from Genbank VRL 22-August-2000
	NN	Wang, Y. et al. Accession No. D10934 downloaded from Genbank VRL 03-February-1999
	OO	Okamoto, H. et al. Accession No. D31972 downloaded from Genbank VRL 07-February-1999
	PP	Greene, W. et al. Accession No. U14231 downloaded from Genbank VRL 27-January-1995
	QQ	Odeberg, J. et al. Accession No. U24602 downloaded from Genbank VRL 23-February-1996
	RR	Hall, W. et al. Accession No. L19380 downloaded from Genbank VRL 11-August-1994
✓	SS	Liu, K. et al. Accession No. M74888 downloaded from Genbank VRL 02-August-1993

Examiner Signature

T. Wenzel

Date Considered

5/14/04

\*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609.  
 Draw line through citation if not in conformance and not considered.  
 Include copy of this form with next communication to applicant.

Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE**  
**STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet

5

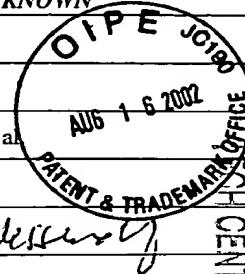
of

6

Attorney Docket Number

**COMPLETE IF KNOWN**

Application Number	09/463,098
Filing Date	May 15, 2000
First Named Inventor	Nicosia, A. et al.
Group Art Unit	1629
Examiner Name	Bhauji, T. <i>Weiner</i>

RECEIVED  
U.S. PATENT AND TRADEMARK OFFICE  
CENTER FOR TRADEMARKS

AUG 20 2002

1600/2000

<b>OTHER NON PATENT LITERATURE DOCUMENTS</b>		
Examiner Initials*	Cite No.	Include name of the author, title, date, page(s), volume-issue number(s) and place of publication.
TW	TT	Han, J. et al. Accession No. L12354 downloaded from Genbank VRL 27-July-1994
.	UU	Scarselli, E. et al. Accession No. X79672 downloaded from Genbank VRL 28-June-1995
.	VV	Kato, N. et al. Accession No. D12952 downloaded from Genbank VRL 28-May-1999
.	WW	Kato, N. et al. Accession No. D16566 downloaded from Genbank VRL 04-February-1999
.	XX	Chen, P. et al. Accession No. M84754 downloaded from Genbank VRL 14-July-1994
.	YY	Okamoto, H. et al. Accession No. D14853 downloaded from Genbank VRL 01-February-2000
.	ZZ	Kato, N. et al. Accession No. S24080 downloaded from Genbank VRL 29-May-1998
.	AAA	Sarashina, T. et al. Accession No. S35631 downloaded from Genbank VRL 07-May-1999
.	BBB	Weiner, A. et al. Accession No. S62395 downloaded from Genbank VRL 25-August-1993
.	CCC	Yamaguchi, K. et al. Accession No. S70291 downloaded from Genbank VRL 23-September-1994
.	DDD	Tokita, H. et al. Accession Nos. D88472, D17503 downloaded from Genbank VRL 07-February-1999
.	EEE	Abe, K. et al. Accession No. D10687 downloaded from Genbank VRL 01-February-2000
.	FFF	Kato, N. et al. Accession No. D43651 downloaded from Genbank VRL 10-November-1997
.	GGG	Okamoto, H. et al. Accession No. D14305 downloaded from Genbank VRL 01-February-2000
✓	HHH	Kato, N. Accession No. X60590 downloaded from Genbank VRL 05-April-1992

Examiner Signature

*T. Weiner*

Date Considered

5/14/04

\*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609.

Draw line through citation if not in conformance and not considered.

Include copy of this form with next communication to applicant.

Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE**  
**STATEMENT BY APPLICANT**  
*(use as many sheets as necessary)*

Sheet

6

of

6

Attorney Docket Number

IT0019P

<b>COMPLETE IF KNOWN</b>	
Application Number	09/463,098
Filing Date	May 15, 2000
First Named Inventor	Nicosia, A. et al.
Group Art Unit	1627
Examiner Name	Bhatti, T. <i>checked</i>

*OPPE JONES  
AUG 16 2000  
PATENT & TRADEMARK OFFICE  
RECEIVED  
02001  
2000*

**OTHER NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No.	Include name of the author, title, date, page(s), volume-issue number(s) and place of publication.
Tan	III	Seki, M. et al. Accession No. D30613 downloaded from Genbank VRL 07-February-1999
	JJJ	Weiner, A. Accession No. X53131 downloaded from Genbank VRL 05-August-1995
	KKK	Odeberg, J. et al. Accession No. U24619 downloaded from Genbank VRL 23-February-1996
	LLL	Ogata, N. et al. Accession No. M62382 downloaded from Genbank VRL 10-June-1996
	MMM	Tokita, H. et al. Accession Nos. D88474, D17505 downloaded from Genbank VRL 07-February-1999
	NNN	Scarselli, E. et al. Accession No. X79669 downloaded from Genbank VRL 23-July-1997
	OOO	Jones, R. et al. Accession No. A48766 downloaded from Munich Information Center for Protein Sequences (MIPS) 19-May-1995
	PPP	Okamoto, R. et al. Accession No. PQ0835 downloaded from MIPS 14-July-1994
	QQQ	Higashi, R. et al. Accession No. D48776 downloaded from MIPS 07-April-1994
	RRR	Higashi, R. et al. Accession No. C48776 downloaded from MIPS 07-April-1994
✓	SSS	Kato, N. et al. Accession No. PC1193 downloaded from MIPS 30-September-1993

Examiner Signature

*T. Misra, Jr.*

Date Considered

5/14/04

\*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609.

Draw line through citation if not in conformance and not considered.

Include copy of this form with next communication to applicant.